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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/731,432	12/10/2003	Helmut D. Link	246472003920	5128
25227 7590 08/19/2008 MORRISON & FOERSTER LLP 1650 TYSONS BOULEVARD SUITE 400 MCLEAN, VA 22102				
EXAMINER				
SHAFFER, RICHARD R				
ART UNIT		PAPER NUMBER		
3733				
MAIL DATE		DELIVERY MODE		
08/19/2008		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/731,432

Applicant(s)

LINK ET AL.

Examiner

Richard Shaffer

Art Unit

3733

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 April 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7, 9-18 and 20-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 22 is/are allowed.
- 6) ☒ Claim(s) 1-7, 9-18, 20, 21 and 23-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB-08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Priority

Applicant's statements regarding priority is found persuasive and all claims except for 20 as stated by applicant are afforded priority back to March 12th, 2002.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-7, 9-18, 21, 23, 24 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Michelson (US Patent 6,159,214).

Michelson discloses a system comprising:

[First Interpretation] a guide device (700) has a moveable opening for guiding a tool; a projecting adjustment instrument having a rod (152), a wedge shaped intervertebral plate (154) having a surface area less than the surface area of an intervertebral space inherently capable of being centered with respect to the intervertebral space, and an intermediate adjustment portion (758); the adjustment portion (758) is displaceable along the rod (152) with the use of the grooves (156); the moveable opening of the guide device (700) is larger than the intervertebral plate (154);

and the tip of the plate (154), the shoulder of plate that juts out from the rod (152), and bores (155, 714, 720a-b, and 721a-d) can all act as x-ray markers in the A-P and L-M directions.

[Second Interpretation] a guide device (700) has a moveable opening for guiding a tool; a projecting adjustment instrument having a rod (152, 758) and a wedge shaped intervertebral plate (154) having a surface area less than the surface area of an intervertebral space inherently capable of being centered with respect to the intervertebral space; the guide device can be pushed onto a free end of the adjustment rod (152, 758) with engagement features (737a and 723a) creating a non-rotational fit; the drill guide further has four drill gauges (721a-d) with two pairs offset by 180 degrees; the guide device (700) could be rotated by 180 degrees while maintaining functionality; the shoulder of plate that juts out from the rod (152), and bores (155, 714, 720a-b, and 721a-d) can all act as x-ray markers in the A-P and L-M directions.

[Third Interpretation] a guide device (1110) has a moveable opening for guiding a tool; a projecting adjustment instrument having a rod (152) and a wedge shaped intervertebral plate (154) inherently capable of being centered with respect to the intervertebral space; the plate having a surface area less than the surface area of an intervertebral space; the guide device (1110) defines at least guide holes (1130, 1132, as well as unlabeled portions) to receive pins (1228a-b like shown in Figure 68); and a spreader (1100) that can hold maintain the pins parallel to one another.

In regard to claim 18, the limitation of "a clear distance" is functional language. What one person would consider clear would be different than another, further, if one

had a smaller opening prepared, then the plate of Michelson would inherently be at least 70% of the distance.

Michelson disclose a method (**Column 5, Line 19 through Column 6, Line 36; Figures 1-72**) comprising: removing an intervertebral disk (**Step 1**); introducing an intervertebral plate (**154**) into the intervertebral space (**see Figure 11D**); the plate itself is an X-ray marker extending in the anterior-posterior direction [or one could assign the tapered portion from rod portion (**152**) and plate (**154**) or threading on the rod itself (**152**)]; applying a guide device (**100; Steps 5 and 6**) projecting in the ventral direction from the plate (**154**); working the spaces (**Steps 10 and 11**) for fitting the prosthesis.

Claim 20 is rejected under 35 U.S.C. 102(b) as being anticipated by Hanson et al (US Patent Application Publication 2002/0068941).

Hanson et al disclose (**Page 7, Paragraphs 0110-0112; Figures 25-29**) a set of rasps to match the shape and configuration of the implant for an intervertebral prosthesis; the rasps having a surface (**607**) without teeth; and the rasps have a handle (**603/604**).

Response to Arguments

Applicant's arguments filed on April 30th, 2008 have been fully considered but are only partially persuasive.

In response to claim 1 stating Michelson does not anticipate the newly added limitation of "operable as an aiming line along an anterior-posterior axis," it matters not if Michelson appreciated the usability of the structure of his device or not. What matters is whether the device is inherently capable of performing the claimed function, which as

previously stated, it is. Numerous components could define a line which could be interpreted as being an aiming line during various portions of the procedure or merely placed within the body under x-ray control.

In response to claim 16 stating Michelson does not disclose a device which is positioned by the adjustment rod via complementary surfaces shaped to give a non-rotational fit stating specifically that the posts 734a and 734b perform the stated function instead of a specific surface shape. The complementary shapes of posts 734a and 734b allow the components to engage; therefore the surface shape does allow the two components to engage in a non-rotational manner.

In response to claim 18 now reciting "configured to be connected to the pins to hold" the pins parallel and asserted as not being anticipated by Michelson, the interpretation of 1110 being the spreader element receiving pins such as 1228a and 1228b is still felt to read upon the claimed language. It is felt clear that the device 1110 would not allow any pins located within the holes to come together or move relative to one another.

In response to claim 23, applicant asserts that the holes on block 700 or 1110 are all offset to the left or right. For 700, the holes located behind 723a and 723b are both medial along with the previously specified holes 1130 and 1132 in guide 1110 being medial.

In response to claim 20 of the assertion that Hanson does not disclose the newly added limitation of the largest rasp height being substantially similar to that of the other rasps, the height corresponding to that of the prosthesis as well as a leveled surface on

the rasp without teeth. All of the rasps would be of "substantially similar" height as they all are placed within the intervertebral space with only slight differences based upon anatomy, but more or less substantially the same. Further, a leveled surface can merely mean a smooth surface, as in one without any protrusions which as previously described the surface 607 of Hanson meets.

In regard to claim 22, applicant asserts that Butterman et al do not anticipate the claim, the examiner agrees. Due to the numerous claim limitations, Butterman et al do not disclose the step of "positioning and securing an intervertebral plate of an adjustment instrument in the intervertebral space" as required by the claim as a whole. It is merely noted that plate-like elements are passed through and secured as shown in Figures 18 and 19B, but not used in the manner specified in claim 22 (i.e. sliding a hub of a guide device onto an adjustment rod projecting from the intervertebral plate).

Allowable Subject Matter

Claim 22 is allowed.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard Shaffer whose telephone number is (571)272-8683. The examiner can normally be reached on Monday-Friday (7am-5pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Richard Shaffer/
Examiner, Art Unit 3733
/Eduardo C. Robert/
Supervisory Patent Examiner, Art Unit 3733